



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/668,665

09/23/2003

Jean-Claude Yvin

P08425US00/BAS

1061

881 7590 04/15/2009

STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

04/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,665	Applicant(s) YVIN ET AL.	
	Examiner ERIC S. OLSON	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 28, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's communication submitted January 28, 2009 wherein claim 1 is amended and claims 4, 8, and 9 are cancelled. This application was filed September 23, 2003, and makes no priority claims.

Claims 1, 5-7, 10, and 11 are pending in this application.

Claims 1, 5-7, and 10 as amended are examined on the merits herein.

Applicant's amendment, submitted January 28, 2009, with respect to the rejection of instant claims 8 and 9 under 35 USC 112, second paragraph, for reciting an additional active agent while the base claim requires the method consist essentially of administering the claimed saccharide, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 28, 2009, with respect to the rejection of instant claim 8 under 35 USC 112, first paragraph, for lacking written description for a method comprising administering a potentiator, has been fully considered and found to be persuasive to remove the rejection as the rejected claim has been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 28, 2009, with respect to the rejection of instant claims 8 and 9 under 35 USC 112, first paragraph, for lacking

Art Unit: 1623

enablement for methods comprising administering all possible chemotherapeutic agents and potentiators, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 28, 2009, with respect to the rejection of instant claims 1 and 5-10 under 35 USC 112, first paragraph, for lacking enablement for methods of treating all of the recited diseases, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been amended to limit the scope to certain specific cancers that are enabled by Applicant's disclosure. Therefore the rejection is withdrawn.

Applicant's arguments, submitted January 28, 2009, with respect to the rejection of instant claims 1 and 5-7 under 35 USC 102(b) for being anticipated by Ning et al., have been fully considered and found to be persuasive to remove the rejection as the language of the disclosure of Ning et al. is unclear as to whether it includes straight-chain unbranched oligosaccharides. Therefore the rejection is withdrawn.

Applicant's arguments, submitted January 28, 2009, with respect to the rejection of instant claim 10 under 35 USC 103(a) for being obvious over Ning et al., have been fully considered and found to be persuasive to remove the rejection as the language of

Art Unit: 1623

the disclosure of Ning et al. is unclear as to whether it includes straight-chain unbranched oligosaccharides. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 28, 2009, with respect to the rejection of instant claim 9 under 35 USC 103(a) for being obvious over Ning et al. in view of Gunasekera et al., has been fully considered and found to be persuasive to remove the rejection as the language of the disclosure of Ning et al. is unclear as to whether it includes straight-chain unbranched oligosaccharides. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 28, 2009, with respect to the rejection of instant claim 8 under 35 USC 103(a) for being obvious over Ning et al. in view of Merck, has been fully considered and found to be persuasive to remove the rejection as the language of the disclosure of Ning et al. is unclear as to whether it includes straight-chain unbranched oligosaccharides. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1623

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kong et al. (PCT International publication WO01/44263, Reference and English translation included with PTO-892)

Kong et al. discloses oligosaccharides with immunostimulating and antitumor activity. (p. 6, first paragraph of the translation) The oligosaccharides fall within a general formula [I] that includes both branched (when m is 1-4) or unbranched (when m is 0) saccharides. (p. 6 last paragraph - p. 7 second paragraph of the translation) In a preferred embodiment, the saccharides are all glucose and are linked by beta 1,3 linkages. (p. 7 paragraphs 5 and 6, p. 8 first paragraph, translation) Tetrasaccharides and pentasaccharides are preferred. (p. 8 third paragraph, translation) The oligosaccharides can be used in a method for treating cancer by injection or oral administration. (p. 22, third paragraph, translation) They work by inducing expression of LI-2 and TNF-alpha in the peripheral blood. (p. 22, last paragraph, translation) The saccharides are disclosed in pharmaceutical formulations comprising pharmaceutical solutions and tablets. (p. 45 last paragraph - p. 47 first paragraph, translation) Kong et al. does not explicitly disclose an unbranched saccharide having all the characteristics recited in the instant claims.

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat a subject in a method according to Kong et al. using an unbranched beta 1,3-glucan tetrasaccharide or pentasaccharide. One of ordinary skill in the art would have been motivated to use a 1,3-beta-glucan tetrasaccharides or

Art Unit: 1623

pentasaccharide because all of these qualities (length, 1,3-beat bonds, glucose residues) are disclosed by Kong et al. as preferred embodiments of the invention. One of ordinary skill in the art would have been motivated to use an unbranched saccharide because Kong et al. discloses in formula [I] that the saccharides can be unbranched. One of ordinary skill in the art would reasonably have expected success because these saccharides are included within the broad teaching of Kong et al. as having the disclosed antitumor activity.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
4/13/2009